

WHAT IS CLAIMED IS:

1. An extended release acetaminophen composition comprising a plurality of discrete particles containing acetaminophen, which, when
5 contained within a gelatin capsule and assayed in a USP Apparatus I rotating basket at 50 rpm in 900 mL of phosphate buffer at pH 5.8 and 37°C exhibits about 40 percent to about 53 percent acetaminophen dissolution at one-half hour, about 50 percent to
10 about 68 percent dissolution at 45 minutes, about 57 percent to about 77 percent acetaminophen dissolution at one hour, about 82 percent to about 92 percent acetaminophen dissolution at two hours and about 100 percent dissolution at six hours.

15 2. The extended release acetaminophen composition according to claim 1 comprising particles containing acetaminophen coated on sugar/starch seeds, said particles present as a blend of both an
20 immediate release and a controlled release form.

3. The extended release acetaminophen composition according to claim 2 wherein said controlled release particles comprise a sugar/starch
25 seed particle coated with a plurality of layers of acetaminophen and magnesium stearate that are bound with povidone, and said acetaminophen-containing layers are coated with a plurality of layers of a mixture of povidone and magnesium stearate.

30

4. The extended release acetaminophen composition according to claim 3 wherein the weight ratio of acetaminophen to magnesium stearate in said

48

00446243 090390

controlled release particles is about 5:1 to about 10:1, and acetaminophen comprises about 70 to about 80 weight percent of said controlled release particles.

5

5. The extended release acetaminophen composition according to claim 2 wherein said immediate release particles comprise a sugar/starch seed particle coated with a plurality of layers of a mixture of acetaminophen, starch and cross-linked carboxymethyl cellulose bound with povidone.

6. The extended release acetaminophen composition according to claim 5 wherein said immediate release particles contains acetaminophen, starch and cross-linked carboxymethyl cellulose in a weight ratio of about 13-16:1:1.5-2, respectively, and acetaminophen constitutes about 60-70 weight percent of the particles.

20

7. The extended release acetaminophen composition according to claim 2 wherein said immediate release particles and said controlled release particles are present in said blend at a weight ratio of about 1:1 to about 1:1.5, respectively.

8. The extended release acetaminophen composition according to claim 2 wherein said blend also contains coated sugar/starch seeds that are free of acetaminophen.

30

9. The extended release acetaminophen composition according to claim 8 wherein said immediate release particles, said controlled release particles and said coated sugar/starch seeds are present in said blend at a weight ratio of about 1:1-1.5:0.1-0.25.

10. The extended release acetaminophen composition according to claim 1 wherein said beads comprise an acetaminophen particle coated with each of a first, second and third layer, wherein said first and third layers are comprised of hydroxypropyl cellulose and said second layer is ethylcellulose.

11. The extended release acetaminophen composition according to claim 10 wherein the weight ratio of each said first, second and third layers on a bead is about 1:4-6:1, respectively, and said acetaminophen constitutes about 92 to about 94 weight percent of each bead.

12. The extended release acetaminophen composition according to claim 10 wherein said beads are sized so as that about 90 percent by weight pass through a 20 mesh sieve screen and about 90 percent by weight are retained on an 80 mesh sieve screen.

13. A process for treating a human patient that has difficulty swallowing acetaminophen in tablet, caplet or capsule form that comprises the steps of:

(a) distributing an effective amount of the acetaminophen coated particles of claim 1 in a palatable medium to form an acetaminophen particle-containing medium; and

5 (b) administering said acetaminophen particle-containing medium to said human patient.

14. The process according to claim 13
wherein said human patient is a child about 3 months
10 to about 14 years old.

15. The process according to claim 14
wherein said child is febrile.

add 7
a²

add 7
B¹